



Appendix 3. DMC Ethics Codebook

Codes

Name	Description
1 Experience and qualifications Members	
1a. how joined DMC	
1b. Duration served in DMC	
1c. Qualifications	
1d. Members of DMC	
1d(i). representation of communities, patients	
1e. Number and types of DMCs they served on	

Name	Description
2. How DMC are structured	
2a. DMC terminology	
2b. Purpose why form DMCs	
2e. appropriateness of DMC need	
2f. (in)dependence of DMCs	
2h. Workload	
2i. issues around conflicts	
2j. Relationships with others (RECs/IRBs, sponsors, PIs, FDA)	
3. What does DMC oversee?	
3c. nature and types of the studies for DMC decisions	
3d. safety issues in studies	
3e. study integrity	
3f. on efficacy	

Name	Description
3g. whether study sample represents target population	
4. How DMC make decisions	
4a. decision making processes	
4b.. guidance documents	
4c. blinding of DMC	
4d. Expertise needed	
4e. Presentation of info for DMC to make decisions	
5. DMC training	
4a. DMC training - or lack of	
6. Ethics expertise and experts in DMC	
6a. Ethicists in DMC, roles, reasons	
6b. perceptions about ethicists in DMC	
6c. DMC ethics training	

Name	Description
6d. DMC members skills on ethics	
6e. Ethics related decision-making, issues and processes	
7. Ethical challenges	
7a. Balancing interests of participants against societal interests	
7b. Weighing risks/burdens against benefits for participants	
7c. obligations to inform participants	
7d. Disregarding stopping boundary	Stopping the trial early before stopping boundary is crossed or continuing the trial after stopping boundary was crossed
8. Impact of COVID pandemic	
8a. Virtual meetings	
8b. Interpretation of study results	What parts of the data reflect something COVID-related rather than being related to the intervention?
9. Ideas for reforming DMCs	
9a. Presenting data more clearly	Chair + reporting statistician should work together to present data so it is digestible and shows the stakes of the decision

Name	Description
9b. Consultation of external ethicists	If not enough ethicists to have one on the committee, could consult others as needed
10. Great quotes	Code to be double-coded only with another code—just here to capture great quotes that might be good to include in the titles or body of the papers we will eventually write
11. Disagree	Only to be used if we do primary coding and secondary coding, and secondary coder disagrees with the application of a particular code